UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 4, 2016

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No. 10324-185
Data Package 435068
Product Name: Maquat 25-12

From: Wallace Powell, Biologist
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Through: Jenny Tao, Senior Toxicologist
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To: Julie Chao, PM 33/Aline Heffernan
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Mason Chemical Company

FORMULATION FROM PROPOSED LABEL:

Active Ingredient:	% by weight
Glutaraldehyde (EPA PC Code 043901)	25.7
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride (EPA PC Code 069105)	5
Didecyl dimethyl ammonium chloride (EPA PC Code 069149)	7.5
Other Ingredient(s):	61.8
Total:	100.0

BACKGROUND

The registrant has submitted a registration amendment for Maquat 25-12. The purpose of the amendment includes making historical acute toxicity data references and updating the precautionary and First Aid labeling.

RECOMMENDATION

The registrant has cited acute oral toxicity and acute dermal toxicity studies from this same product registration, under MRIDs 47707503 and 47707504, respectively. The two studies were accepted in a 6/26/2009 PSB review, DP 364459, and were assigned Toxicity Category III.

For acute inhalation toxicity, the registrant has submitted a study, MRID 49818705. The study is acceptable in support of Acute Toxicity Category III. A review of the study is attached to this memorandum.

The registrant has requested waivers for eye irritation and dermal irritation, under MRID 49818706. The two data requirements are waived. Acute Toxicity Category I is assigned, based on the likelihood of severe irritation.

For dermal sensitization, the registrant has cited a study from this same product registration, under MRID 47707505. The study was accepted in an 8/5/2009 PSB review, DP 367599, with a result of Non-sensitizer. (Note: At the time of that review, the study had not yet received an MRID. However, the review identifies the study by its laboratory study number, which corresponds to MRID 47707505.)

Summary

The acute toxicity profile of Maquat 25-12 is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	47707503	III	Previously accepted
Acute Dermal Toxicity	47707504	III	Previously accepted
Acute Inhalation Toxicity	49818705	III	Acceptable
Primary Eye Irritation	49818706	I	Waived
Primary Dermal Irritation	49818706	I	Waived
Dermal Sensitization	47707505	Non-sensitizer	Previously accepted

Product labeling comments

1. Precautionary statements indicated in the *Label Review Manual*:

   Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing [dust, vapor or spray mist]. Wear [specify appropriate protective eyewear such as goggles, face shield, or safety glasses] and [specify appropriate protective clothing and gloves]. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

2. PPE statements indicated in the 2007 RED (Reregistration Eligibility Decision) for Glutaraldehyde, for end-use products intended for occupational use:

   Long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron.

3. Comments on the human-hazard precautionary and First Aid statements in the proposed labeling (dated "6-28-16"):

    - No adverse comments.
    - Compliance with the RED and with specific PPE statements in the *Label Review Manual* is a product-by-product determination. The Agency PM is welcome to discuss the labeling with the PSB reviewer if they wish.

Note: This product meets the 40 CFR 152.170(b) criteria for consideration of possible Restricted Use Classification.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OCSPP 870.1300)

Product Manager: 33
MRID No.: 49818705
Reviewer: W. Powell
Study Completion Date: 1/22/2013
Report No.: 12-119-6

Testing Laboratory: Tox Monitor Laboratories, Inc.
Author: Michael Kukulinski

Quality Assurance (40 CFR §160): Included

Test Material: Maquat 25:12
Concentration: Gravimetric – 0.61 mg/L
Nominal – 5.08 mg/L
Chamber Type: Nose-only

Species: Rat, Sprague-Dawley derived
Sex: 5 Males and 5 Females
Age: 8-12 weeks
Weight: 220-269 grams
Source: Harlan Sprague Dawley

Summary:

1. **Estimated LC_{50}**: > 0.61 mg/L
2. **Toxicity Category**: III
3. **Classification**: Acceptable

Deviations from Guideline 870.1300 and other comments:

1. The MMAD (mass median aerodynamic diameter) slightly exceeded the Guidelines. Based on the slightness of exceeding the Guideline limit, and the clear outcome indicated by the test animals' responses, the MMAD level is not a critical deficiency.
2. The relative humidity in the exposure chamber was below the Guideline for the first hour.

Results:

Male and female rats were exposed nose-only to the test atmosphere at 0.61 mg/L. All animals survived exposure and gained body weight during the study. Adverse clinical signs following exposure were limited to ocular discharge in three males during post-exposure hours 1 through 4. No gross abnormalities were noted for any animals when necropsied at the end of the 14-day observation period.

Reported Mortality

Exposure Concentration (mg/L)	Number of deaths / number tested		
	Males	Females	Combined
0.61	0 / 5	0 / 5	0 / 10

Exposure Chamber Atmosphere

Exposure Conc. (mg/L)	MMAD* (µm)	GSD	% of Particles < 4.7 µm
0.61	4.03	2.87	53.8

*Average of two measurements taken at appropriate intervals. The two MMADs were consistent with each other, as were the GSDs.

Exposure Chamber Environment

Exposure Level (mg/L)	0.61
Chamber Volume (L)	400
Total Airflow Rate (Lpm)	119-121
Temperature (°C)	19.7-20.9
Relative Humidity (%)	17-43